

SPL Process ER/DL Meeting

Meeting Minutes

Sept 24, 2014

Chair of today's meeting: Mary Beth Wilusz

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. SPL Jamboree – Feedback

The video of the National Library of Medicine's 2014 SPL/DailyMed Jamboree has been archived and is available for viewing utilizing this hyperlink:

<http://videocast.nih.gov/Summary.asp?File=18627&bhcp=1>.

The presentations from the aforementioned SPL event will be made available soon.

Major Discussion Topics:

- Data mining for downstream users
- Use of RxNorm by pharmacopeia
- Use of RxNorm for e-prescribing
- Images in SPL

2. Updates to DailyMed web site – any feedback?

Discussion:

- People seem to like it
- This was noted in the opening remarks.
- SetIDs for permanent links are not as obvious. You can find it either in the address or – on the labels@fda.gov website
- If you do a product NDC search, you will get results that are for a totally different product. This issue has been sent to NLM. (Perrigo and Reed Tech have seen this issue.)
- Send any comments, John Kilbourne at NLM is very interested in receiving your comments. Please send questions and issues to John.Kilbourne@nih.hhs.gov

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3. Updates to DRLS web pages CDER Direct - any feedback?
archived webinar link:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm413379.htm>

Discussion:

- CDER gave a demo of another option for a SPL creation tool last week. This seems to be meant as an improvement for using Xforms.
- See the presentation for more information. After the submission, the tool will provide an update as to the status of the submission.
- Only validation pre-submission is the Light Validator.
- Issue: Would not allow one user to import their old file. The tool was built for IE8, but this would not run on IE9. They may need to back save the file to IE8 format.

4. Federal Register notice: Report on REMS Standardization

<https://www.federalregister.gov/articles/2014/09/23/2014-22513/report-on-the-standardization-of-risk-evaluation-and-mitigation-strategies-availability>

Discussion:

- Stay tuned and we will get more information about this.
- Separate SPL file.
- Provided feedback at Jamboree on how to approach discussing this with industry – ie provide story board.

5. Reminder: Draft Guidance: Lot Distribution Reports

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/ucm411976.htm>

Discussion:

- Reminder: This will be mandatory starting Jun 1, 2015.
- Separate SPL file.

6. SPL Images: There is a new federal register notice about providing images, with instructions for providing product for the creation of images to post on Daily Med. The images used to be created by Pillbox. This will be done in the future by CP3I. Herb O'Brien presented on this at the Jamboree.

- Providing SPL images and Rx images.
- SPL images submitted voluntarily
- Currently no charge for taking these images. If funding is limited in the future, there may be a charge.

7. Combination Product Coding –

- Not being validated at this point.
- FDA provided definitions of the various combination product codes.
- Difficulty: There may be more than 1 code that could work.

- Combination product web site:
<http://www.fda.gov/combinationproducts/aboutcombinationproducts/ucm101496.htm>
- For Definitions of the Combination product categories, go to the SPL Resources page – terminology files
- <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

SPL Terminology Files for Validation

- [Active Ingredient-Active Moiety Relationship/Basis of Strength marketing category.\)](#)
- [Additional Validation Files \(XML\)](#)
- [Combination Product Category Types \(XML and Excel\)](#)
- [Cosmetic Product Category Codes](#)

8. Open questions from the team